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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,689

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Michael James Fox

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EXAMINER

HAND, MELANIE JO

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,689	<b>Applicant(s)</b> FOX, MICHAEL JAMES	
	<b>Examiner</b> MELANIE J. HAND	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/3/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on July 3, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

2. Claims 11 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5, 7, 8, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosengreen (WO 99/02985 A1).

With respect to **claim 1**: Rosengreen discloses a device for non-invasively detecting or

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monitoring a medical condition in a mammal. The device comprises a member in the form of absorbent article 2 adapted to be worn upon the body of the mammal to receive at least some of a bodily fluid excreted by the mammal. The member carries one or more marker ingredients in the form of an indicator chemical that interact with one or more components of the bodily fluid to generate a color. The interaction is characteristic of said medical condition in the mammal, namely the onset of childbirth via detection of amniotic fluid.

With respect to **claim 2**: The member comprises a bodily fluid absorbent pad in the form of absorbent mat 6 sandwiched between an inner, next to the body, bodily fluid permeable layer in the form of porous cover 20, and an outer bodily fluid impermeable layer in the form of sheet 22. (Figs. 2, 3, Page 7, line 21 - Page 8, line 3)

With respect to **claim 5**: The one or more marker ingredients disclosed by Rosengreen are applied to said absorbent pad 6.

With respect to **claim 7**: The article disclosed by Rosengreen absorbs and contains fluid therein and is herein considered to be a container for collection of said bodily fluid.

With respect to **claim 8**: The container disclosed by Rosengreen includes a component in the form of an absorbent mat 6 through which said bodily fluid passes in receipt by said container 18, said one or more marker ingredients being applied to said component 6.

With respect to **claim 13**: Rosengreen discloses a non-invasive method for detecting or monitoring a medical condition in a mammal, namely the onset of childbirth. The method

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comprises detecting a color change in a marker ingredient in the form of an indicator chemical that interacts with one or more components of a bodily fluid excreted by the mammal, i.e. amniotic fluid, to generate a color. The interaction is characteristic of the medical condition in the mammal, i.e. the pH of the amniotic fluid present. The marker ingredient is carried by a carrier member in the form of an absorbent pad 18 worn by the mammal which receives at least part of the bodily fluid excreted by the mammal.

With respect to **claim 14**: Rosengreen discloses a method for producing a device for non-invasively detecting or monitoring a medical condition in a mammal. The device comprises a member in the form of an absorbent pad adapted to be worn upon the body of the mammal, i.e. held directly adjacent to the body, to receive at least some of a bodily fluid excreted by the mammal, i.e. amniotic fluid. The method comprises applying to that member one or more marker ingredients in the form of an indicator chemical which are to interact with one or more components in the bodily fluid so as to generate a color. The interaction is characteristic of the medical condition in the mammal inasmuch as it detects the pH of the incoming fluid and changes color if the pH of the fluid is within the range of the pH of amniotic fluid, which indicates the medical condition of the onset of childbirth.

5. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Gropp et al (DE 3504527) (English translation).

With respect to **claim 1**: Gropp discloses a device for non-invasively detecting or monitoring a medical condition in a mammal. The device comprises a member in the form of a urine collection bag adapted to be worn upon the body of the mammal to receive at least some of a bodily fluid excreted by the mammal, inasmuch as the bag is connected with the patient to

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collect the urine. The member carrying one or more marker ingredients in the form of fabric strips containing reagents 11-14 which interact with one or more components of the bodily fluid (urine) to generate a color, said interaction being characteristic of the medical condition in the mammal, e.g. glucose level. (whole document)

With respect to **claim 7**: The member comprises a urine collection bag worn by the mammal for collection of said bodily fluid inasmuch as the bag is connected with the patient to collect the urine.

With respect to **claim 8**: The bag disclosed by Gropp includes a component, namely an indicator component 10 containing the reagent strips in bag walls 9, over which said bodily fluid passes in receipt by said bag, said one or more marker ingredients 11-14 being applied to the fabric strips of said component 10.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosengreen ('985).

With respect to **claim 15**: The marker ingredients are applied to said member by means of a dye, i.e a liquid carrier. Rosengreen does not explicitly disclose that the liquid carrier contains a resinous binder. However the resinous binder is necessary to form a cohesive pigment within the liquid carrier so that the dye is effective on its intended substrate. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Rosengreen such that the one or more marker ingredients are applied by means of a liquid carrier containing a resinous binder with a reasonable expectation of success to ensure the marker ingredients remain in the desired place and function as intended in the absorbent pad.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosengreen in view of any one of Jitoe (U.S. Patent No. 5,766,212), Everhart (U.S. Patent No. 5,468,236) and Olson et al (U.S. Patent No. 6,297,424), each one individually.

With respect to **claim 3**: Rosengreen discloses that the marker may be applied to an area directly adjacent the vaginal opening, which could include the inner layer since the inner layer is directly adjacent the vaginal opening during wear. Rosengreen does not explicitly disclose applying the marker to the inner layer. However, since Rosengreen is disclosing an external absorbent article having an inner layer, or topsheet, and topsheets having indicators thereon are

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well known in the art as supported by any one of Jitoe, Everhart and Olson. These indicators provide visible indication to a caregiver or wearer upon detaching the article that the diaper is wet or soiled, thus necessitating replacement of the article. Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Rosengreen such that the indicator is applied to the inner layer with a reasonable expectation of success to provide clear visible indication of the presence of a bodily fluid and that the article is soiled.

10. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosengreen ('985) in view of Olson et al (U.S. Patent No. 6,297,424).

With respect to **claim 4**: Rosengreen discloses that the marker ingredients are applied to the absorbent mat 6 and thus does not disclose one or more marker ingredients applied to the inner face of said outer layer 22 that are observable through said outer layer. Olson discloses an absorbent article having an inner layer 42, outer layer 40 and absorbent pad 38 therebetween wherein one or more marker ingredients in the form of character graphics 70 made from ink are applied to the inner face and are observable through said outer layer 40. Olson discloses that this allows the caregiver to determine when the diaper is wetted with urine and should be replaced. Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Rosengreen such that the marker ingredients are instead applied to the inner face of the outer layer to allow indication of the medical condition to a caregiver.

With respect to **claim 6**: Rosengreen discloses that the marker ingredients are applied to the absorbent mat 6 and thus does not disclose one or more marker ingredients that comprise first and second marker ingredients. Olson discloses an absorbent article having an inner layer 42,



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outer layer 40 and absorbent pad 38 therebetween wherein one or more marker ingredients in the form of character graphics 70 made from ink are applied to the inner face and are observable through said outer layer 40. Olson discloses that this allows the caregiver to determine when the diaper is wetted with urine and should be replaced. Therefore, it would be obvious to one of ordinary skill in the art to modify the article of Rosengreen such that the marker ingredients are instead applied to the inner face of the outer layer to allow indication of the medical condition to a caregiver. The article of the combined teaching of Rosengreen and Olson comprises one or more marker ingredients comprising first marker (urine) and second marker (amniotic fluid) ingredients. The first marker ingredient as disclosed by Olson is applied to the outer layer, and said second marker ingredient as disclosed by Rosengreen is applied to said absorbent pad. Interaction of said bodily fluid with said first marker ingredient (ink) as disclosed by Olson results in the dissolution and the migration into said absorbent pad of a substance (the ink) which then interacts with said second marker ingredient to generate another visible indication, i.e. the absence of the indicator color in the pad due to a lower pH level than the amniotic fluid indicator is made to detect.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gropp in view of Boehm et al (DE 10101679 A1) (English translation).

With respect to **claim 9**: Gropp discloses that a tube in the form of flexible inlet hose 2 feeds said bodily fluid to said bag. Gropp discloses that the one or more marker ingredients are applied to the bag wall and thus does not disclose that they are applied to an inner face and/or a component of tube 2. Boehm discloses a tube wherein one or more marker ingredients in the form of test substances 6 are applied to an inner face of the tube. Boehm discloses that this

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eliminates the need for separate collecting/measurement and diagnostic steps. Thus, it would be obvious to one of ordinary skill in the art to modify the device of Gropp by replacing the flexible inlet hose/tube 2 with the tube disclosed by Boehm to eliminate the need for a separate step of collecting the urine in the collection bag, and then subsequently allowing analysis via the indicator component in the bag wall.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosengreen ('985) in view of Batich et al (U.S. Patent No. 6,306,422).

With respect to **claim 10**: Rosengreen does not disclose that said one or more marker ingredients are incorporated into a slow-release composition. It is also noted that applicant has not explicitly and clearly defined the phrase "relatively lengthy period of time", thus the claim is given its broadest reasonable interpretation by the examiner. Batich discloses a composition for controlled release of active ingredients to detect the presence of bacteria in urine, indicating a urinary tract infection. Since the detection of such infection facilitates immediate and proper treatment, it would be obvious to one of ordinary skill in the art to modify the article of Rosengreen so as to comprise marker ingredients incorporated into a slow or controlled release composition as disclosed by Batich to allow detection of bacteria in urine as an indication of urinary tract infection. With regard to the limitation "to provide detection and monitoring of said medical condition over a relatively lengthy period of time", since the article of Rosengreen as modified by Batich meets the limitation of one or more marker ingredients incorporated into a slow release composition, the composition is fully capable of providing detection and monitoring over a relatively lengthy period of time.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/  
Examiner, Art Unit 3761